UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,450	06/08/2006	Shozo Tanada	5328-20PUS	6951

27799 7590 09/15/2010

COHEN, PONTANI, LIEBERMAN & PAVANE LLP
551 FIFTH AVENUE
SUITE 1210
NEW YORK, NY 10176

EXAMINER	
CHAWLA, JYOTI	
ART UNIT	PAPER NUMBER
1781	

MAIL DATE	DELIVERY MODE
09/15/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,450	TANADA ET AL.	
	Examiner	Art Unit	
	JYOTI CHAWLA	1781	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's submission filed on 6/30/2010 has been entered as compliant. Claim 8 has been amended and claims 13-20 have been added to the current application. Claims 1-20 are pending and examined in the current application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Rejection of claim 8 made under 35 U.S.C. 112, second paragraph, for being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, has been withdrawn based on applicant's amendment of 6/30/2010.

Claims 13 and 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites "bacteriostatic agent in a dried solid form", which makes the limitation recited in claim 13 unclear. Claim 13 depends from claim 7, which depends from claim 6 and which in turn depends from claim 1. Claims 7 and 6 do not qualify the bacteriostatic agent form a solid and independent claim 1 recites "bacteriostatic agent against thermo acidophilic bacilli (TAB), comprising a puree or a fruit juice obtained from acerola". According to claims 1, 6 and 7, bacteriostatic agent is present is a puree or juice and not in solid form as claimed. Thus, recitation of "bacteriostatic agent in a dried solid form" in claim 13 is unclear. For the purposes of examination a food or drink comprising acerola juice or puree will be considered relevant as prior art.

Claim 13 is also indefinite for the recitation of concentration “0.055 and 10% by mass”, as it is unclear whether the proportion of bacteriostatic agent is being measured with respect to the total mass of acerola juice or puree or by mass of the food or drink as recited in claim 13. Clarification and/or correction is required.
Claim 16 is indefinite for reciting the same limitation as claim 13 “by mass” without further qualifying the phrase "the mass" further.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

A) Claims **1-2 and 4-12 and 16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuchs et al (EP 5071571, English abstract), hereinafter Fuchs, in view of the combination of IDS reference to Nair et al (WO 01/15553 A1), hereinafter Nair, and Oita (with English abstract).

Regarding **claim 1**, Fuchs et al , hereinafter Fuchs discloses of beverage comprising acerola puree (English abstract), as claimed. Fuchs does not disclose the compounds present in acerola product, however, Nair discloses that fruits, including acerola

comprise of phytochemicals, such as flavonoids, polyphenols including anthocyanins, anthocyanadins (hydrolyzed anthocyanins), cyanindins etc.(Nair, Page 3, lines 1-3 and 20-26, page 10, lines 1-12, Page 10, lines 22 to page 11, line 20). Further, polyphenols which have been known to show inhibitory activity thermo tolerant bacteria (Alicyclobacillus acidoterrestris), as disclosed by IDS document by Oita (see English Abstract) wherein Oita discloses of polyphenolic compounds found in grape varieties. However, fruits including Acerola also contain polyphenols including anthocyanins, anthocyanadins (hydrolyzed anthocyanins), flavonoids, cyanindins etc, as disclosed by Nair (Nair, Page 3, lines 1-3 and 20-26, Page 10, lines 6-12, Page 10, lines 22 to page 11, line 20). Thus, product as disclosed by Fuchs comprises a puree or a fruit juice containing polyphenolic compounds. The aspect of inhibiting thermo tolerant bacteria is a feature of the polyphenols as shown by the Oita abstract. Thus, at the time of the invention one of ordinary skill in the art was aware that polyphenols have inhibitory activity towards thermo tolerant bacteria Alicyclobacillus. One of ordinary skill also had the knowledge that food products obtained from Acerola fruit, its juice, puree etc contain polyphenols (Fuchs and Nair). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention that polyphenols from Acerola pulp will be present in the beverage disclosed by Fuchs, and that the polyphenols of the beverage will exhibit an inhibitory effect on the growth of thermo tolerant bacteria to a certain extent. One of ordinary skill would have been motivated to modify Fuchs and disclose the polyphenolic compounds at least for the purpose of educating the consumer about additional beneficial effects of the beverage.

Regarding **claims 4, 5 and 11**, the limitation of thermo acidophilic bacilli (TAB) being of genus Alicyclobacillus acidoterrestris, has already been discussed above in claim 1.

Regarding **claim 2**, Fuchs abstract is silent about the acerola fruit substance being “a dried substance”. However, Nair discloses of making dry fruit extracts (Page 15, 20-30, also see page 16). Thus, dried fruit and vegetable extracts were well known in the art at the time of the invention (Nair, pages 11-16) for their long shelf life and ease of storage.

Therefore, it would have been a matter of routine determination for one of ordinary skill in the art at the time of the invention to modify Fuchs and make a beverage composition comprising dried Acerola component. One of ordinary skill would have been motivated to do so at least for the purpose of achieving a beverage comprising acerola with a longer shelf life.

Further, regarding the limitation of making a product that “is to be added to food or drink”, as recited in **claim 12**, Fuchs as applied to claim 2, teaches of a beverage, which is a food or drink comprising acerola (i.e., bacteriostatic agent, as discussed above regarding claim 1), however, addition of dried extracts to foods and beverages was well known in the art at the time of the invention. For example, Fuchs, discloses of enriching the drink with minerals like trisodium phosphate etc., (abstract and title), i.e., adding minerals. Further, Nair discloses that the composition comprising fruit flavonoids, may be formulated into a gel, a capsule, a tablet , a syrup, a beverage or a powder suitable to use as a dietary food supplement (Page 3, 27-29 and page 16, lines 23-27). Thus, dietary ingredients that can be added to foods and beverages to enhance the taste or flavor or nutrient content of the food was notoriously well known, e.g., sprinkling sugar on fruit or in tea/coffee. Therefore, it would have been well within the purview of one of ordinary skill to modify Fuchs based on the teachings from Nair and make acerola fruit component as a dried product, which can be added to food or drink (as discussed above regarding claim 2). One of ordinary skill would have been motivated to modify Fuchs at least for the purpose of providing a nutritive ingredient in a shelf stable form that can be added to foods and drink at the time of consumption in desired amount based on the nutrition and organoleptic experience desired. One would have been further motivated to do so at least for the purpose of providing acerola component in the form that is suitable to use as a dietary food supplement as taught by Nair (Page 3, 27-29 and page 16, lines 23-27).

Regarding **claims 6-7**, Fuchs discloses of making a fruit drink comprising acerola puree or juice, and regarding the specific limitation of "inhibiting or blocking bacterial growth” has already been discussed above regarding claim 1.

Further regarding **claims 9-10**, Fuchs beverage comprising acerola juice or puree, which meets the limitations of "a food or drink comprising bacterial growth inhibitor...agent of claim 6" of claim 9 and "inhibiting or blocking a bacterial growth …agent of claim 6, into the food or drink" as recited in claim 10.

Regarding the newly amended **claim 8**, Fuchs as applied to claim 1 discloses of making a fruit drink comprising acerola puree or juice (English abstract), which fulfils one of the alternatives recited in claim 8, i.e., the limitation of "comprising adding a puree or a fruit juice obtained from acerola fruit...to a food or drink in the state of liquid or semisolid". Further, applicant has not disclosed any specific amount that would constitute "an effective amount", of acerola juice or puree in order to meet the claimed limitations recited in claim 8. Thus, in the absence of a specific concentration or amount, the fruit drink disclosed by Fuchs which comprises acerola puree or juice meets the limitations of "a method for inhibiting or blocking a bacterial growth in a food or drink…liquid or semi liquid" as claimed.

Regarding the limitation of **claim 16** "bacteriostatic agent as the dried substance" it is noted that claim 16 depends from claim 8. Fuchs as applied to claim 8, teaches a drink comprising acerola puree, which as per the recitation of claim 8 is one of alternative ways in which acerola component can be added to foods or beverages to achieve bacteriostatic effect, the option of adding acerola component as dried substance as recited in claims 8 and 16 becomes an optional limitation and is treated as such. Thus, the rejection of claim 8, also applies to claim 16.

B) Claims **3, 19-20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuchs, Nair and Oita further in view of Shanbrom (WO 99/13889), hereinafter Shanbrom.

Claims 1-2, 4-12 and 16 have been rejected over Fuchs, in view of the combination of and Nair and Oita above.

Fuchs teaches of a beverage comprising acerola puree or juice, as disclosed in claim 1, however is silent as to the puree or the fruit juice being "desugared". Desugaring fruits to remove juices and sugars was well known in the art at the time of the invention. Nair discloses that during extraction, juice of fruits may be separated from the pulp (Page 14, lines 3-20). Shanbrom discloses of extracting colors (anthocyanins) and antibacterial and antifungal compound from cranberry press cake, which is waste product left after juice has been extracted (Page 3, summary of invention), i.e., desugared. Thus, making dried products from desugared fruits was well known in the art at the time of the invention and it would have been a matter of routine determination for one of ordinary skill in the art at the time of the invention to modify Fuchs and utilize a desugared Acerola component, at least for the purpose of obtaining the fibrous and phenolic components from the fruit without any of the high calorie sugar. One of ordinary skill would have been motivated to do so at least for the purpose of utilizing an inexpensive and low calorie ingredient which is a by-product of another industry to obtain a beneficial component that can be added to foods and beverages for its known antibacterial properties.

The limitations recited in **claims 19-20** are the same as recited in claims 4 and 3 respectively. Thus, claims 19 and 20 are rejected for the same reasons as provided for claims 4 and 3 respectively.

C) Claims **13-15 and 17-18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuchs, Nair and Oita further in view of the combination of Cirigliano et al (US 6120823), hereinafter Cirigliano and IDS reference to Seiki et al (JP 2002-017319, English abstract only), hereinafter Seiki.

Claims 1-2, 4-12 and 16 have been rejected over Fuchs, in view of the combination of and Nair and Oita above.

Fuchs as applied to **claims 1, 7 and 8**, discloses of beverage comprising acerola puree (English abstract), as claimed. Fuchs does not specifically disclose of bacteriostatic

compounds obtained from acerola puree, however the recitation of "bacteriostatic agent against thermo acidophilic bacilli (TAB), comprising a puree or a fruit juice obtained from acerola", is a recitation of intended use of acerola puree. It is noted that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Therefore, given that Fuchs teaches of a food product with acerola puree, and that fruits including acerola contain polyphenols including anthocyanins, anthocyanadins (hydrolyzed anthocyanins), flavonoids, cyanindins etc, as disclosed by Nair (Nair, Page 3, lines 1-3 and 20-26, Page 10, lines 6-12, Page 10, lines 22 to page 11, line 20) and that polyphenols have bacteriostatic activity towards thermo tolerant bacteria (Alicyclobacillus acidoterrestris), as disclosed by IDS document by Oita (see English Abstract), it follows that the composition must also meet the recitation of the intended use of the composition; i.e., "bacterial growth inhibitor or bacteriostatic agent against thermo acidophilic bacilli (TAB), comprising a puree or a fruit juice obtained from acerola".

Fuchs is silent regarding the concentration of bacteriostatic agent obtained from acerola, however, addition of antimicrobial compounds to foods was well known in art at the time of the invention, as disclosed by Cirigliano and Seiki. Further, addition of flavoring compounds, such as phenolic acid, was also known for specific antimicrobial effect on bacteria including alicyclobacillus species (Cirigliano Column 2, lines 13-16). Regarding the specific amount Cirigliano discloses 25 to 2000 ppm or parts per million or more in foods for antimicrobial benefits (Column 2, lines 24-25 and 34-35), i.e., 0.002 to 0.2% by weight of the food product. Seiki discloses of bacterial growth inhibitor for TAB bacteria, as claimed where the antimicrobial is added to a beverage in an amount ranging from 0.01 to 10 parts by weight (Abstract last 2 lines), which also overlaps with the claimed concentration ranges recited by the applicant for **claims 13-15, 17-18**. Thus, addition of acerola puree or dried acerola component to foods and drinks was known at the time of the invention (Fuchs), and was also known that acerola puree

comprises bacteriostatic agent (Nair and Oita). Further, it was also known that addition of bacteriostatic agents to food or beverage in the claimed range of the applicant was known to one of ordinary skill in the art at the time of the invention, (as disclosed by Cirigliano and Seiki). Cirigliano and Seiki disclose amount of bacteriostatic agents in food or beverage products which overlap with applicant's claimed range. Accordingly, it would have been obvious to one of ordinary skill in art to use or combine (teaching of Cirigliano and Seiki) in the range as claimed, because it has been held that where the general conditions of the claims are discloses in the prior art, it is not inventive to discover the optimum or workable range by routine experimentation. See In re Aller, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955). One of ordinary skill in the art at the time of the invention would have been motivated to do so at least for the purpose of including acerola component in an amount to achieve optimal antibacterial effect in the food or beverage product.

Further regarding the overlapping of ranges between the invention and prior art composition it is noted that in the case where the claimed ranges "overlap or lie inside the ranges disclosed by the prior art" a prima facie case of obviousness exists (In re Wetheim, 541 F2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990)).

Response to Arguments

Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection necessitated by applicant's amendments to previously examined claims and addition of new claims 13-20.

Applicant's arguments against Fuchs, Nair, Oita are still relevant and responded below. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the

instant case Fuchs teaches of food product comprising acerola puree and Nair is relied upon to show that acerola puree or juice comprises polyphenols or flavonoid compounds. Oita is being relied to show that polyphenols have bacteriostatic effect on TAB bacteria as claimed. Thus at the time of the invention one of ordinary skill had knowledge that TAB bacteria can be inhibited by polyphenols, Acerola puree contains polyphenols and food products comprising acerola puree were known. Therefore, it would have been a matter of routine determination for one of ordinary skill in the art at the time of the invention that since the polyphenolic compounds present in grapes and berries and acerola have similar anti inflammatory properties, one of ordinary skill would have a reasonable expectation that polyphenols present in acerola will have an inhibitory effect on TAB that is similar to the grape polyphenols of Oita.

Further, in response to applicant's argument that the teaching of Oita does not apply (Remarks, page 8, last paragraph) and "the combination of the above two cited references and Oita would not have rendered the claimed invention obvious" (Remarks, page 9, Para 2, last 2 lines), the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Also the attention is invited to the invention as claimed in independent claim 1 which recites "a bacterial growth inhibitor or a bacteriostatic agent against thermo acidophilic bacilli (TAB, Comprising a puree or a fruit juice obtained from an acerola …fruit as an active ingredient thereof". Wherein the use of acerola puree or juice as bacteriostatic agent is an intended use limitation. It is noted that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Therefore, given that Fuchs teaches of a food product with acerola puree, and

that fruits including acerola contain polyphenols including anthocyanins, anthocyanadins (hydrolyzed anthocyanins), flavonoids, cyanindins etc, as disclosed by Nair (Nair, Page 3, lines 1-3 and 20-26, Page 10, lines 6-12, Page 10, lines 22 to page 11, line 20) and that polyphenols have bacteriostatic activity towards thermo tolerant bacteria (Alicyclobacillus acidoterrestris), as disclosed by IDS document by Oita (see English Abstract), it follows that the composition must also meet the recitation of the intended use of the composition; i.e., "bacterial growth inhibitor or bacteriostatic agent against thermo acidophilic bacilli (TAB), comprising a puree or a fruit juice obtained from acerola".

Thus, applicant's arguments have been fully considered but have not been found persuasive and claims 1-20 are rejected for the reasons of record.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTI CHAWLA whose telephone number is (571)272-8212. The examiner can normally be reached on 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JC/
Examiner
Art Unit 1781

/Keith D. Hendricks/
Supervisory Patent Examiner, Art Unit 1781